SEP 26 2000

K001244

510(k) SUMMARY

Citizen Watch Company, Ltd.
Models CH-631B, CH-631D, CH-632B and CH-632D
Blood Pressure Meters

SUBMITTER'S NAME, ADDRESS, TELEPHONE NUMBER, CONTACT PERSON AND DATE PREPARED

Citizen Watch Company, Ltd.
Medical Device Section, NP Development Department
1-12, 6-Chome, Hon-cho
Tanashi-shi, Tokyo, 188 JAPAN

Contact: Joseph D. Edmondson, Jr., Esq.
Foley & Lardner
3000 K Street, N.W., Suite 500
Washington, D.C. 20007
Phone: (202) 672-5300
Fax: (202) 672-5399

Date Prepared: April 17, 2000

NAME OF DEVICE

Trade Name:	Models CH-631B, CH-631D, CH-632B and CH-632D Blood Pressure Meters
Common Name:	Digital Wrist Sphygmomanometer (blood pressure meter)
Classification Name:	System, Measurement, Blood Pressure, Non-Invasive (21 C.F.R. § 870.1130)

PREDICATE DEVICE

Omron Healthcare, Inc., Model HEM-609, Wrist Blood Pressure Monitor

INTENDED USE

The Citizen CH-631 and CH-632 digital wrist sphygmomanometers (blood pressure meters) are intended to be used for oscillometric measurement of systolic and diastolic blood pressure and pulse, are intended to be sold over-the-counter and to health care professionals, and not primarily under the order or direction of a physician.

DEVICE DESCRIPTION

The Citizen CH-631B, CH-631D, CH-632B and CH-632D digital wrist sphygmomanometers are noninvasive blood pressure measurement systems that measure systolic and diastolic blood pressure and pulse from the user's left wrist. Each unit is contained in a hard plastic housing that contains a user interface panel, microprocessor and air pump and is connected an adjustable wrist cuff. The user interface panel has a power switch and a liquid crystal display ("LCD"). In the case of models CH-632B and CH-632D, the user interface panel also has a start switch.

The device measures blood pressure through the use of an automatically-inflating wrist cuff. The cuff automatically deflates during blood pressure measurement. Models CH-631B and CH-632B have a memory function that displays the last blood pressure readout when the system is turned on. Model CH-631D and CH-632D have a memory function that allows the user to retain seven (7) prior blood pressure measurements.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The models covered by the 510(k) submission are substantially equivalent to the predicate device, Omron Healthcare, Inc.'s Model HEM-609. The Citizen models differ in certain respects, including a different power source (2 "LR03" size batteries in place of 2 "AAA" size batteries in the predicate device) and a different procedure for deflation of the wrist cuff (electromagnetic valve in place of mechanical release valve in the predicate device). Citizen has determined that these differences have no influence on the correct measuring and the accuracy of systolic and diastolic blood pressure.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 26 2000

Citizen Watch Co., LTD
c/o Foley and Lardner
Attorneys at Law
3000 K Street NW
Suite 500
Washington, DC 20007
Attn: Joseph D. Edmondson

Re: K001244
Trade Name: Blood Pressure Meter, Models CH-631B, CH-631D
Regulatory Class: II (two)
Product Code: DXN
Dated: August 11, 2000
Received: August 14, 2000

Dear Mr. Edmondson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K001244

Device Name: Citizen Watch Company, Ltd. Models CH-631B, CH-631D, CH-632B, and CH-632D Blood Pressure Meters

Indications For Use:

The Citizen CH-631 and CH-632 digital wrist sphygmomanometers (blood pressure meters) are intended to be used for oscillometric measurement of systolic and diastolic blood pressure and pulse are intended to be sold over-the-counter and to ~~health care~~ professionals, and not primarily under the order or direction of a physician.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ~~ANOTHER PAGE IF~~ NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K001244

(Optional Format 3-10-98)